REMARKS

Review and reconsideration on the merits are requested.

Claim Rejections - 35 U.S.C. §112 (1st Paragraph)

This rejection is respectfully traversed.

The Examiner states the specification, while being enabling for treating hyperlipidemia associated with gestational toxicosis in rats, does not reasonably provide enablement for preventing hyperlipidemia or IUGR associated with gestational toxicosis, or preventing or treating IUGR or hyperlipidemia associated with gestational toxicosis in any subject other than a rat.

As the Examiner states in the Action at page 4, lines 6-7:

"IUGR is a common but not necessary complication of preeclampsia (von Versen-Hoeynck and Powers, 2007)".

The present specification teaches that preeclampsia (gestational toxicosis) is one of the causes of IUGR (see p.1, lines 21-27 of the present specification). Therefore, one of ordinary skill in the art would understand that by treating gestational toxicosis, IUGR caused by gestational toxicosis can be improved or treated.

The Examiner concludes that the results achieved in IUGR and preeclampsia model rats using L-NAME do not correlate in humans in a predictable fashion based on the teaching in Buhimschi et al (Action, page 4, lines 7-18).

However, Buhimschi et al actually state:

"We and other authors have previously shown that, in pregnant rats, chronic competitive inhibition of NO synthesis during pregnancy with L-arginine analogues causes hypertension, proteinuria and fetal growth retardation without affecting gestational length. Glomerular

damage and histopathological changes in the placental bed similar to those in human pre-eclampsia have also been reported." (see page 32, the paragraph bridging the left and right columns, last 15 lines, underscore added).

Thus, in fact, the L-NAME induced rat model actually has been used as an animal model predictive of effectiveness in treating human preeclampsia.

Further, there is no disclosure or evidence in Buhimschi et al to indicate that such a preeclampsia rat model cannot be used to correlate to human patients.

The present Inventors have shown that the present compound has a remarkable treating effect for gestational toxicosis, specifically improving the elevation of maternal urinary protein (Table 4) and plasma triglyceride levels (Table 5). In addition, it is shown that the present compound has a remarkable improving effect for IUGR.

Thus, although the Examiner notes that Applicant did not indicate that the increase in fetal body weight (Table 1) between the test and control groups was statistically significant, in this experiment, in comparison with the control group (3400 mg, 513 mg decrease from the normal group), the fetal body weight in the test group (3550 mg, 363 mg decrease from the normal group) was markedly improved with about a 30% improvement. Further, the incidence of static gangrene in the tip of fetal extremities was also markedly improved (present specification p. 11, lines 20 to 23 and Table 3).

Thus, Applicants respectfully submit that the specification is enabling for treating gestational toxicosis and improving IUGR caused by gestational toxicosis in human patients.

Withdrawal is requested.

Claim Rejections - 35 U.S.C. §102

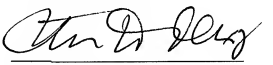
The compound disclosed in Yanagi et al is the same as the compound of the present invention.

Applicants believe that the Examiner has, in fact, fairly treated the claims as involving treating or preventing (Action, page 2, full paragraph at the bottom of the page), and respectfully amend all claims into the corresponding method claims.

Regarding "improvement of intrauterine growth retardation caused by gestational toxicosis", Applicants consider that basis resides in the disclosure that the present compound improved markedly the fetal weight loss associated with IUGR (see Example 1, from line 29 of p.9 to line 1 of page 10), and improved markedly static gangrene in the tip of fetal extremities (see Example 2, lines 20-23 of p.11) in a gestational toxicosis model (line 17 of p.10). In addition, "gestational toxicosis is one of causes of IUGR" (line 28 of p.1).

Consideration of these claims is requested.

Respectfully submitted,



Peter D. Olexy, P.C.
Registration No. 24,513

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: December 4, 2008